

Remarks

Claim 1 has been amended to add the limitations of claims 5 and 6. Claims 5 and 6 have been cancelled. Accordingly, no new matter is involved. Claims 10 and 19 have been amended to properly show the change in dependence and claim 14 has been amended to now depend from claim 1 instead of now cancelled claim 5. Accordingly, no new matter is involved. Claims 7, 14 and 15 have been amended to replace the term “actuator” with “drive spring”. Support for this can be throughout the specifications and drawings as originally filed. Accordingly, no new matter is involved.

In the previous office action claims 10 and 19 were objected to for not properly showing the desired change in dependence. As noted above, the appropriate corrections have been made. Therefore, it is respectfully requested that the Examiner withdraw these objections.

Claim Rejections – 35 USC § 102

Claims 1 to 21 stand rejected by the examiner under 35 U.S.C § 102(b) as being anticipated by US Patent No. 5,478,316 to *Bitdinger et al.* (“*Bitdinger*”).

Specifically, the examiner asserts that, with regard to claim 1, *Bitdinger et al.* teach an injection device comprising: a housing (Fig. 3 member 12) adapted to receive a syringe (Fig. 3 member 30) having a discharge nozzle and having a boot that covers its discharge nozzle (Figs. 3 and 4 boot 36), so that the syringe is movable between a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharged nozzle extends from the housing through an exit aperture (see transition in Figs. 5 and 6); a releasable locking mechanism that retains the syringe in its retracted position (Fig. 3 interaction between 28A and 66B, Col. 5 lines 40-60); and a housing closure member that can occupy a first position, in which it locates on the housing and prevents the locking mechanism from being released, and a second position, in which it does not prevent the locking mechanism from being released, the first position of the housing closure member being one in which it engages the boot, so

that movement of the housing closure member to its second position results in removal of the boot from the syringe (Fig. 4 closure member 16).

Moreover, with regard to claims 5 and 6, the examiner refers to actuator 66C (Fig. 3), drive 46 (Fig. 3), biasing member 56 (Fig.3), and return member 40 (Fig.3).

With respect to currently amended claim 1, it is well settled that to anticipate a claim, the reference must teach every element of the claim, see M.P.E.P. § 2131. Moreover, in order for a prior art reference to be anticipatory under 35 U.S.C. § 102 with respect to a claim, "[t]he elements must be arranged as required by the claim," see M.P.E.P. § 2131, citing *In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Furthermore, in order for a prior art reference to be anticipatory under 35 U.S.C. § 102 with respect to a claim, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim," see M.P.E.P. § 2131, citing *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). Applicant respectfully asserts that the rejection does not satisfy at least one of these requirements.

Claim 1 recites means for biasing the syringe from its extended position (i.e. the position in which the discharge nozzle extends through the exit aperture) to its retracted position (i.e. the position in which the discharge nozzle is contained within the housing). In an embodiment consistent with the present invention, the means for biasing acts to retract the syringe into the housing following delivery of the medicament.

Also recited in claim 1 is a return mechanism to release the syringe from the action of the drive spring, whereupon the means for biasing restores the syringe to its retracted position.

Bitdinger lacks means for biasing the syringe from an extended position to a retracted position. *Bitdinger* discloses just one biasing means which acts on the syringe 30: the constant force spring 56. As stated in column 1, lines 60 to 62 of *Bitdinger*, the constant force spring is for moving the syringe assembly with respect to the housing and

towards the skin of the patient. In other words, the constant force spring 56 biases the syringe from a retracted position (as shown in figure 5) to an extended position (as shown in figure 6) and not vice versa. In that respect, the constant force spring 56 corresponds to the drive spring recited in claim 1.

Bitdinger also lacks a return mechanism to release the syringe from the action of the drive spring. Irrespective of the stage of operation of the device of *Bitdinger*, the constant force spring 56 (i.e. the drive spring) always acts, via the rod 46 and/or the driver 58, on the syringe – either on the cartridge 30 or the piston 32. To prevent the exposed needle 38 from being a hazard following delivery of the medicament, *Bitdinger* teaches a sleeve 28 which is extendable over the exposed needle under the action of sleeve spring 40 (which is not, as the examiner asserts, a return mechanism to release the syringe from the action of the drive spring).

Claims 2 to 4 and 6 to 21 stand rejected by the examiner under 35 U.S.C § 102(b) as being anticipated by US Patent No. 5,478,316 to *Bitdinger*. Claims 2 to 4 and 6 to 21 depend from base claim 1, and thus inherit all the limitations of claim 1. Each of claims 2 to 4 and 6 to 21 therefore set forth limitations not recited by *Bitdinger* for the reasons given above. Hence Applicant respectfully asserts for the above reasons claims 2 to 4 and 16 to 21 are patentable over *Bitdinger*.

Applicant submits that all claims are now fully allowable over the prior art cited by the Examiner. Therefore, Applicants respectfully requests that the Examiner withdraw all rejections to Applicants' claims. In conclusion, Applicant respectfully requests that the Examiner re-examine and favorably reconsider Applicant's claims in the form of a Notice of Allowance.

Respectfully submitted,

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